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Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

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Citation (APA):
Miller, A., & Helt-Hansen, J. (2011). *Establishing and using an uncertainty budget for dose to product*. Poster session presented at 16th International Meeting on Radiation Processing, Montreal, Canada.

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Establishing and using an uncertainty budget for dose to product

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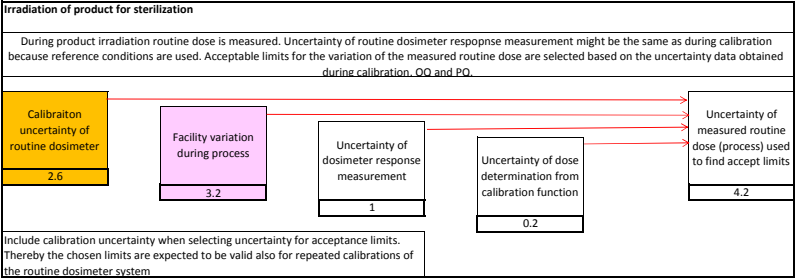
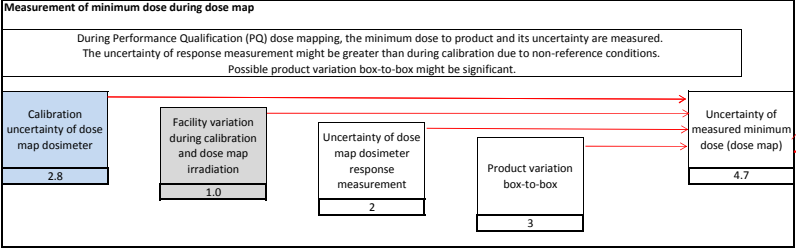
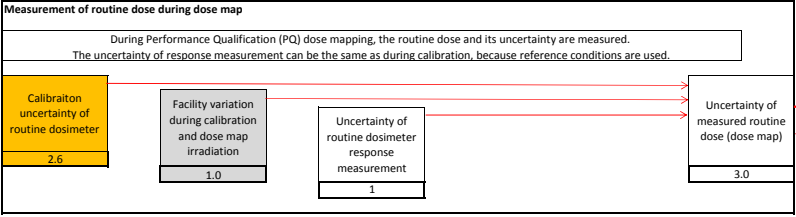
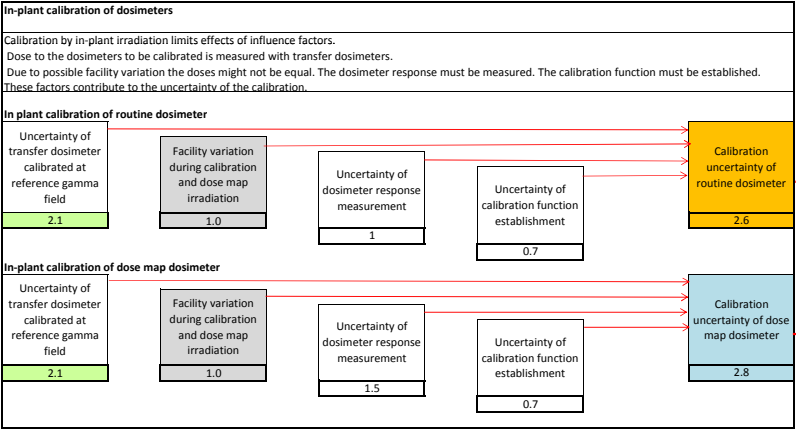
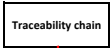
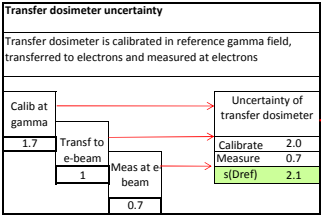
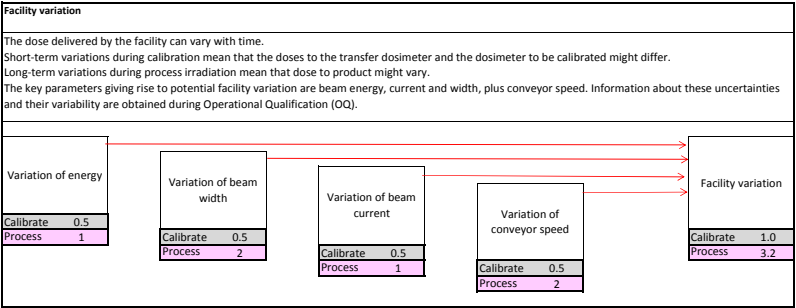
This poster shows the main components of uncertainty to be taken into account for irradiation of product. Radiation sterilization of medical devices is taken as an example, but the principles apply to any product irradiation process. The uncertainty analysis is carried out considering minimum dose only. A parallel exercise can be carried out with respect to maximum dose.

The intention of this poster is to show the link between traceability and uncertainty, and to discuss how to use these in specifying the irradiation process.

Example:
Facility: 10 MeV Electron accelerator
Calibration of dosimeters: In-Plant calibration method
Process: Medical device sterilization
Sterilization dose D_{ster} : 25 kGy

Uncertainty budget - VIM definition:
statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination

All uncertainty components are given at 1 s.d.
Uncertainty values are given as examples only!



Total uncertainty of dose to product used to find Target dose

$s_{(total)}$ 5.2

The total uncertainty of dose to product is the combined uncertainty of minimum dose and routine dose. The uncertainty of the transfer dosimeter used for calibration of both dosimeter systems is only counted once.

Required routine dose is calculated as

$$D_R(Req) = D_R(meas) * (D_t / D_{min}(meas))$$

Limits for acceptable variation of routine dose are based on uncertainty for routine dose during process.

Warning limits: 2.5 s.d.
Action limits: 3.5 s.d.

Determine required routine dose $D_R(Req)$

Determine accept limits for routine dose

Determine target dose D_{tar}

$k = 2$
 D_t (kGy) 27.9

Target dose D_t is calculated as

$$D_t = D_{ster} / (1 - k * s_{(total)} / 100)$$

D_{ster} = Sterilization dose
 k = number of standard deviations that minimum dose must be greater than sterilization dose